IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, TAKEDA PHARMACEUTICALS AMERICA, INC., and ETHYPHARM, S.A., Plaintiffs, v. MYLAN PHARMACEUTICALS INC. Defendant.	:	Civil Action No. 3:11-cv-02506-JAP-DEA

SUPPLEMENTAL DECLARATION OF DR. RUSSELL J. MUMPER

I, Russell J. Mumper, Ph.D., submit this supplemental declaration in support of Defendant Mylan Pharmaceuticals Inc.'s ("Mylan") response to Takeda's Opening Claim Construction Brief and in response to both the Declaration and Deposition of Takeda's expert, Dr. Stephen Byrn.

1. My qualifications, prior testimony and compensation can be found in paragraphs 1-22 of my March 23, 2012 Declaration, which I incorporate herein by reference.

2. The materials I considered in forming my opinions are referenced in Exhibit 2 to my March 23, 2012 Declaration, and are referenced in and attached to this declaration.

I. Dr. Byrn's Definition of a Person of Ordinary Skill in the Art is Not Supported

3. Dr. Byrn's opinion is that a person of ordinary skill in the art would have "at least a college degree in an appropriate field such as pharmacy, pharmaceutical science, chemistry, or chemical engineering, and at least four years of work experience in the field of drug formulation"

(Byrn Declaration, Paragraph 23). His opinion is based in part on a court decision on a formulation involving another drug in the same class as lansoprazole, omeprazole (Byrn Declaration, Paragraph 23). See *In re Omeprazole Patent Litig.*, 490 F. Supp. 2d 381, 517 (S.D.N.Y. 2007) ("[T]he Court finds that a person of ordinary skill in the art would have at least a college degree in a field of natural science such as pharmacy, pharmaceutical science, chemical engineering, or organic chemistry, and at least four years of work experience in the field of drug formulation"). However, this case pertained to tablets intended to be swallowed whole, not orally disintegrating tablets ("ODTs").

4. Dr. Byrn admitted during his deposition that formulating ODTs is more difficult than ODTs (Byrn Deposition, Page 41 lines 20-22 to Page 42 lines 1-10).

> Q. Would you agree that formulating ODTs is certainly more difficult than formulating or manufacturing standard tablets?
> …
> A. Is. I mean, I guess it could be certain standard tablets that had stability problems or something that could be very difficult; but generally, I think it's more difficult to make an ODT than a standard tablet. Yes.

5. Dr. Byrn and I agree that making ODT tablets is more difficult than a standard tablet. Therefore, the person of ordinary skill in the art should have more than a college degree and at least four years of work experience. Dr. Byrn's definition of a person of ordinary skill in the art does not comport with his own testimony and declaration regarding the complexities of ODT technology.

6. While there may be exceptional candidates who, with a bachelor's degree and several years of experience, could conceivably design a drug as claimed, that is far from the norm.

7. I reaffirm my opinion that for the subject matter of the '994 patent and '632 patent, the level of one of ordinary skill in the art as of the filing date of the '994 patent and the

'632 patent would be a person with a Ph.D. in physical pharmacy or physical chemistry, or the equivalent, followed by at least three years of post-doctoral training or practical experience in drug formulation.

II. Takeda's Proposed Construction Allowing for a "± 10%" Standard of Error Is Not Supported by Evidence

8. The person of ordinary skill in the art in reviewing the claims, in light of the specification, would understand the phrase "fine granules having an average particle diameter of 400 µm or less" to be limited to the precise ranges recited therein, particularly given that the patentees used the word "about" in certain portions of the specification, not in others, and that the patentees used the word "about" to modify other terms in the same claim but not with respect to the numerical limitation of 400 µm.

9. The word "about" is not used by the patentees to modify the "average particle diameter" when commenting on the challenges overcome by the invention: "It is very difficult to produce an enteric coated fine granule with an average particle diameter of 400 µm or less…" ('994 Patent, Column 2, lines 41-42). Neither do the patentees use the word "about" when describing the "Disclosure of the Invention" (Column 3, lines 12-20). And of course, "about" is not used in the claims to qualify the "average particle size."

10. Further, the patentees did not use the word "about" in distinguishing the claims over the prior art and instead explicitly relied on the "400 µm or less" limitation to overcome the Examiner's prior art rejections:

> The tablet of claim 1 is characterized by comprising fine granules having an average particle size of 400 µm or less… The asserted art does not teach or suggest the claimed invention… The [Examiner's] rejection should be withdrawn… The fine granules of claim 32 [now claim 29 of the '994 patent] are characterized as having an average particle diameter size of 400 µm or less… The asserted art does not teach or suggest the claimed invention… The [Examiner's] rejection should be withdrawn.

Exhibit 22 (Amendment "B" and Response) at 5-6.

11. Dr. Byrn stated at his deposition that the basis of his opinion on the ± 10% standard of error is from three apparent sources of information: the U.S. Pharmacopeia ("USP"), Snorek paper, and his personal information (Page 149 lines 15-22; Page 150 lines 1-8).

12. Dr. Byrn admits that prior to 1999, there were no publications about the accepted error using laser light diffraction (Page 135, line 16 through Page 136, line 7) (emphasis added):

> Q. …But prior to 1999, there is nothing published about, in terms of what was universally accepted in terms of standards of error for [laser diffraction]…?
> * * *
> A. Well, although there was nothing published prior to '99, it was almost the ***wild west*** out there. I mean, there was ***no limit at all***. It was even bigger.
> Q. So there was no consensus prior to 1999; it was the **wild, wild west**?
> A. ***Yes, I mean, it could be 400 plus or minus 400***.

13. Dr. Byrn went on to state: "Maybe I didn't explain myself. Prior to the USP [which is dated 2009/2010] and the Snorek work [which is dated 2007], the errors [for laser diffraction] were so large that ***people didn't even have a number on them***." (Page 136 lines 17-20) (emphasis added).

14. As of the '994 patent's filing date, there was no universally accepted or published standard of measurement error in the scientific community for laser diffraction.

15. In fact, the version of the USP that was available as of the filing date of the '994 patent (USP 23/NF 18, dated 1995), did not include any accepted standard deviation for laser diffraction, let alone a 10% standard deviation.

16. To understand the standard deviation for laser diffraction, a person of ordinary skill in the art would look to the specifications for the particular machine being used. For example, a person of ordinary skill in the art using the HELOS RODOS laser diffraction device

named in the '994 patent (Column 5, lines 48-50) would look to the product materials which confirm the standard deviation associated with the measurement of a sample of particles.

17. In my March 23, 2012 Declaration, I provided at least two pieces of literature on the known error of the HELOS RODOS. Kesten et al. reports that the "standard deviation" associated with the measurement of a sample of particles using laser diffraction ranges from about 0.4% to 1.0%. (U. Kesten. Control and Optimisation of Cement Quality with Laser Diffraction Particle Size Analysis and Dry Dispersion. 1997, Sympatec; U. Kesten (Exhibit 16 to my March 23, 2012 Declaration) Application of Laser Diffraction with Dry Dispersion for Automatic Particle Size Analysis. November 1993 (Exhibit 17 to my March 23, 2012 Declaration)). Importantly, this information was available to the person of ordinary skill in the art during the relevant time period.

18. Dr. Byrn admits that the Kesten documents would provide guidance to one of ordinary skill (Byrn Deposition, Page 144 lines 6-11).

> Q. But as far as specific information about the specific device, at least, this was available, and that could give some guidance to the person of ordinary skill in the art, right? That would give some guidance?
>
> A. It would give some guidance.

19. Dr. Byrn presented no evidence that the claimed error of 0.4% to 1.0% was incorrect and admitted that he had no experience using this particular device.

20. Dr. Byrn, however, implied that the standard deviation reported for the HELOS RODOS would not be applicable when measuring drug particles because the standard deviation was derived from measuring cement particles (Byrn Deposition, Page 147 lines 6-11). I disagree. The laser diffraction device works in the same fashion no matter the type of particles used. In fact, Kesten (in Application of Laser Diffraction with Dry Dispersion for Automatic

Particle Size Analysis) states many advantages of dry dispersion analysis of the HELOS RODOS equipment is that it performs to specifications with "*all kinds of dry powders*" (Exhibit 17 to my March 23, 2012 Declaration, slide 13) (emphasis added). Dr. Byrn offers no evidence that the manufacturer's stated specifications were incorrect or that the specifications would be different for cement particles versus drug particles.

21. Furthermore, I disagree with Dr. Byrn's suggestion that it is reasonable to assume a 10% deviation applied to all methods for measuring particle sizes. There was no universally accepted standard deviation value that would have been applicable to all available methodologies for measuring particle size. In fact, other methods for measuring particle size, such as sieving and sedimentation, would have been more precise than a 10% standard deviation as of the filing date of the '994 patent. In any event, Dr. Byrn's suggestion that a single standard is applicable to all available methodologies is inconsistent with his deposition testimony where he conceded no such standard existed at the time the '994 patent was filed (Page 135, line 16 through Page 136, line 7).

III. Dr. Byrn, in Forming His Opinion as to the Construction of "400 μm or less", Fails to Consider the Requirement for Maximum Particle Size in the '994 Patent

22. The '994 patent states: "Aside from the average particle diameter of the above 'fine granules', regarding the maximum particle size, the particle diameter **is** practically 425 μm or less, and preferably practically 400 μm or less. Preferably, the particle diameter is practically 300 to 425 μm, more preferably 300 to 400 μm." ('994 Patent, Column 5, line 65 through Column 6, line 3) (emphasis added).

23. This upper limit, according to the specification, allows only for 5 weight percent or less of "inevitable contaminant particles," which are defined as particles having a diameter greater than 425 μm ('994 Patent, Column 6, lines 3-10).

24. A person of ordinary skill in the art would understand that an integral part of the claimed invention is that the maximum particle diameter is 425 μm. Indeed, the specification characterizes the upper end or "maximum particle size" as a requirement to achieve fine granules that will not impart roughness in the mouth.

25. Notwithstanding that the '994 patent has an explicit requirement for maximum particle size, Dr. Byrn fails to reconcile how his definition of average particle size as "400 μm (± 10%) or less", which therefore includes a possible average particle size of up to 440 μm, would fit within the requirement of the '994 patent that the maximum particle size of any one particle is not greater than 425 μm. In fact, Dr. Byrn, during his deposition, was unsure about the maximum particle size requirements defined in the specification (Byrn Deposition, Page 200 lines 7-22, Page 201 lines 1-18):

> Q. And then if you could just look on column 6, lines -- line 6, it has in quotes: "The particle diameter is practically 400 microns or less." Now, is that a reference to the "average particle diameter"?
> …
> A. I am not sure, but the 400 microns is obviously the number in the claim. But I haven't parsed it down that far. I don't know for sure on that one. Another thing, they are saying "practically," and I'm not sure what that means either, 100 percent.
>
> Q. Well, it says here: "`Practically' as used in the 1 particle diameter is practically" -- I mean, it defines it right up there. Do you see that or at least – do you read column 6?
>
> A. I read it. I don't -- I haven't figured it out yet. I will have to do some more analysis.

26. In my opinion, Dr. Byrn's opinion regarding claim construction of the particle size limitation is not supported by evidence and moreover he admits to not having figured out the maximum particle size requirement in the '994 patent at the time he offered his opinion.

IV. Dr. Byrn Admits the Enteric Coating Agent and Sustained Release Agent Are Different Agents

27. Dr. Byrn provides no evidence or an example as to how an enteric coating agent and sustained release agent could be the same methacrylate polymer. It is my opinion, in view of the specification of the '994 patent, that the methacrylate polymers must be different. The methacrylate polymer taught in the '944 patent as an enteric coating agent, L30D-55, is an anionic methacrylate polymer that functions as an enteric coating agent since it is insoluble at low pH and soluble at higher pH, as required for an enteric coating agent. In contrast, the methacrylate polymers taught in the '944 patent as sustained-release agents (NE30D, RL30D, and RS30D) are either uncharged or cationic polymers that could not function as enteric coating agents, by definition. Dr. Byrn fails to acknowledge this important difference.

28. However, Dr. Byrn does acknowledge that an enteric coating agent and sustained release agent have different functional requirements (Byrn Deposition, Page 128 lines 20-22, Page 129 lines 1-10):

> Q. Okay. And it's also in your view that the enteric coating agent is also defined in the patent as a methacrylate copolymer?
>
> A. Correct.
>
> Q. And that's how you define it as well?
>
> A. Well, an enteric coating agent has to also have acid resistance. It has to be a methacrylate copolymer that has acid resistance.
>
> Q. But the sustained release agent doesn't have to?
>
> A. Correct.

29. Therefore, Dr. Byrn failed to provide an example of one methacrylate polymer that could function within the teaching of the '994 patent as both an enteric coating agent and as sustained release agent. He did provide extrinsic examples purporting to show a methacrylate

polymer, known to be an enteric coating agent, that he claims functions as a sustained-release agent (Exhibits 6-13 to March 23, 2012 Byrn Declaration). Importantly, none of these exhibits are at all related to the teaching of the '994 patent. The '994 patent teaches a composition coated by an enteric coating layer wherein said composition comprises a drug-coated inert core which is first coated with a water-soluble polymer layer and then by the enteric coating layer. In addition, none of these extrinsic examples pertain to ODT tablets. Also, importantly, of all of the extrinsic examples provided by Dr. Byrn, only two (Exhibit 9 and Exhibit 13) were available before the '994 patent's filing date. Exhibit 9 (Vasilevska et al.) pertains to several different Eudragits coated directly on drug particles. Exhibit 13 (Holgado et al.) pertains to the formation of complexes of a drug with the anionic enteric coating agent. In sum, Exhibit 9 and Exhibit 13 are not at all related to the teaching of the '994 patent where a drug-coated inert core is coated first with a water-soluble polymer layer and then an enteric coating layer. None of these references support the notion that an enteric coating agent by itself can function as a sustained release agent, nor that a sustained release agent by itself can function as an enteric coating agent.

30. That I have defined a sustained release agent as an agent that when used by itself to coat fine granules, prolongs release of the active ingredient does not mean that tablet is a sustained release tablet. Whether the sustained release agent indeed functions as a sustained release agent does not matter. What matters is that the claims require the presence of both an enteric coating agent and a sustained release agent as those terms are known in the art.

31. Dr. Byrn also failed to provide any evidence to support his claim that the enteric coating agent and sustained release agent could be the same methacrylate polymer in view of the requirement in the '994 specification that the two agents are used in a precise ratio to one another ('994 patent, Column 9; lines 30-32): "The "sustained release agent" is used in an amount of 5 to

30 weight %, preferably 5 to 15 weight %, relative to 100 weight % of the "aqueous enteric polymer agent".

32. Dr. Byrn has further failed to square his opinions with the file history of the '994 patent. In a December 8, 2000 Amendment and Office Action Response, the patentees distinguished prior art cited by the Examiner in order to overcome an obviousness rejection. The patentees stated that the cited reference, EP 761212 ("the '212 patent"), disclosed an effervescent and enteric coated composition that did not contain a sustained-release agent (Exhibit 23 (Amendment A and Response, Defense Exhibit 17)). The '212 patent has numerous references to the formulation having an enteric coating agent, not a sustained release agent (Exhibit 24 (EP 761212), *e.g.*, at p. 5, lines 48-52. In particular, the reference discloses the use of "acrylic copolymers (*e.g.*, Eudragit L30D-55)" as exemplary enteric coating agents.

33. By distinguishing the '212 patent on the basis that it disclosed an enteric coating agent, one of ordinary skill in the art would understand that the patentees took the position that an enteric coating agent was not the same as a sustained release agent. Even more, in allowing the '994 patent, the Examiner specifically noted that: "The cited prior art does not fairly teach or suggest an oral composition comprising a first component which is an enteric coating and a second component with is a sustained-release agent" (Exhibit 25 at 2 (Notice of Allowability, marked as Defense Exhibit 21)).

34. The '994 file history supports my opinion that the enteric coating agent and sustained release agent are different components.

V. Dr. Byrn Admits the Enteric Coating Layer Is a Blend or Admixture of an Enteric Coating Agent and Sustained Release Agent

35. Dr. Byrn states: "Moreover, the '994 patent teaches an enteric coat made from a *blend* of enteric-coating agent and sustained-release agent" (Byrn Declaration, Paragraph 20)

(emphasis added). Dr. Byrn also reinforced that these agents must be in the same layer at his deposition. Dr. Byrn testified that "enteric coating layer" is defined by the claims as a ***blend or admixture*** of an "enteric coating agent" and a "sustained release agent" (Page 57 lines 7-22, Page 54 lines 3-11):

> Q. Now, just with paragraph 20 [of your report], you used the word "blend." What did you mean by "blend"?
>
> A. Any type of admixture of an enteric coating agent, a sustained release agent.
>
> Q. And that would form what's referred to in claim one as an enteric coating layer?
>
> * * *
>
> A. The claim says:
>
> "…which is an enteric coating layer comprising a first component which is an enteric coating agent, a second component which is a sustained release agent."
>
> Q. So?
>
> A. So, yes, I mean, I use those terms. My answer is I am using the terms in the claim.
>
> * * *
>
> Q. This cushioning effect [as mentioned in paragraph 20 of your report], as you understand it, is achieved by this admixture of the enteric coating agent and sustained release agent?
>
> A. I am just defining the admixture as the claim does, as a layer comprising a first component, which is an enteric coating agent, and a second component, which is a sustained release agent.

36. According to Dr. Byrn, this blend constitutes a novel aspect of the claimed invention on which the patentee relied to overcome the Examiner's prior art rejections (Byrn Declaration, Paragraph 20; Byrn Deposition, Page 119 lines 3-12).

37. Each example in the specification of the '994 patent demonstrates that the enteric coating agent, Eudragit L30D-55, and sustained release agent, Eudragit NE30D, are combined to form an admixture in a single coating layer.

38. That the enteric coating layer is an admixture of an enteric coating agent and a sustained release agent is confirmed by the file history of the '994 patent.

39. Independent claims 1 and 32, as originally filed, included the phrase "enteric coating layer" (Exhibit 26 (Original Claims, marked as Defense Exhibit 15)). However, there was no recitation of an "enteric coating agent" or a "sustained release agent." During prosecution, the Examiner rejected claims 1 and 32 on the grounds that they were anticipated and/or obvious in view of the '212 patent (Exhibit 27 (Office Action, marked as Defense Exhibit 16)).

40. The cited '212 patent shares a common inventor with the application which led to the '994 patent: Toshihiro Shimizu (Exhibit 24 (EP 761212)). In order to overcome the rejection, Shimizu submitted a declaration to distinguish the claimed invention over his prior '212 patent (Exhibit 23 (Shimizu Declaration, marked as Defense Exhibit 17)). Shimizu represented to the Examiner that he conducted an experiment to demonstrate the novelty of his application over the '212 patent. Specifically, he performed the process found in Example A of the '212 patent and that of Example 9 listed in the '994 patent specification. According to Shimizu, there was only one difference between the two examples: Example 9 of the '994 specification utilized an admixture of a sustained release agent and an enteric coating agent for the purposes of coating drug granules; whereas, Example A of the '212 patent has only an enteric coating agent. Shimizu concluded that the formulation of Example 9, from the '994 patent, was superior to the formulation in the earlier '212 patent due to the fact that Example 9 comprised an enteric coating layer having a mixture of an enteric coating agent and a sustained release agent. Thus, Shimizu made clear that the addition of a sustained release agent was the distinguishing factor as between the '994 and '212 patents.

41. Along with the Shimizu declaration, the patentees submitted an amendment to the then pending claims (Exhibit 23). It was this amendment that first added the phrase "sustained release agent" into claims 1 and 32. The amendment also cited to the Shimizu declaration as the basis for the '994 patent's alleged novelty. In particular, the patentee stated:

> In support of the asserted non-obviousness, applicants herewith submit the declaration of Mr. Shimizu, a co-inventor of the present invention. The results of the experiments described in this declaration, supervised by Mr. Shimizu, clearly demonstrates that tablets of the present invention (example [9] of the declaration) have superior unexpected properties over that of the cited Shimizu patent (example [A of the 212 patent] of the declaration).

Id. (Amendment A and Response at 7).

42. Notwithstanding the submission of the Shimizu declaration and the supporting amendment, the Examiner once again rejected the claims on the grounds that they were not commensurate in scope with Example 9. The Examiner explained that Shimizu's declaration was directed to a specific tablet having a specific active ingredient (Exhibit 28 (Office Action, Defense Exhibit 18)). The Examiner also indicated that none of the then pending claims recited a degree of hardness or acid resistance.

43. In response, the patentee again amended the claims. Claims 1 and 32 were amended to include limitations relating to hardness, specifying the active ingredient being lansoprazole, and introducing in the claim the phrase "a first component that is an enteric coating agent and a second component that is a sustained release agent" (Exhibit 22 (Amendment B and Response, marked as Defense Exhibit 19) at 3).

44. After making this subsequent amendment, which made clear that the enteric coating layer had both an enteric coating agent and a sustained release agent, the Examiner issued a notice of allowability. Exhibit 25 (Notice of Allowability, marked as Defense Exhibit 21). In fact, the Examiner stated in the notice that "the cited prior art does not fairly teach or

suggest an oral composition comprising a first component, which is an enteric coating, and a second component, which is a sustained release agent."

45. In my opinion, the fact that the Examiner granted the notice of allowability after the patentees amended the claims to include the first component and second component, as well as the Examiner's emphasis that those changes rendered the application allowable, further supports my construction: that a person of ordinary skill in the art would understand that the enteric coating agent and the sustained release agent are separate and distinct agents, *i.e.*, not the same agent.

46. In sum, a person of ordinary skill in the art, after reviewing the file history of the '994 patent, would determine that the patentees characterized the claimed invention in a specific manner to overcome the Examiner's prior art rejections—namely as fine granules having an "enteric coating layer" comprising a blend of an "enteric coating agent" and a "sustained release agent." Indeed, the person of ordinary skill would understand from the file history that this particular combination is the basis for the claimed invention's alleged superiority, when compared to fine granules coated only with an "enteric coating agent." Thus, by amending the claims to include a "first component that is an enteric coating agent and a second component that is a sustained release agent," as well as arguing that such an amendment distinguished the claims from the fine granules coated only with an enteric coating agent as disclosed in the '212 patent, a person of ordinary skill in the art would conclude that the patentees limited the scope of the term "enteric coating layer" such that its plain and ordinary meaning requires an admixture of an "enteric coating agent" and a "sustained release agent."

47. As noted above, Dr. Byrn's opinions and testimony are consistent with Shimizu's description of the enteric coating layer in his declaration: that it is made of a blend of an enteric coating agent and a sustained release agent.

VI. Dr. Byrn's Definition of "Non-Effervescent Excipients" Is Inconsistent With How The Person of Ordinary Skill In The Art Would Understand That Term

48. There are no standards in the art of pharmaceutical formulations in which "non-effervescence" has been defined to permit a certain amount of effervescent excipients.

49. Even today the FDA requires no specific amount of effervescence that is required for effervescent dosage forms, or non-effervescent dosage forms, and this was true at the time the '632 patent was filed (Exhibit 29, FDA Database on Dosage Form Definitions).

VII. The Phrases "Permits to Obtain Reduced ph Influence in the Digestive Tract" and "Permits to Obtain … Reduced Influence of Viscosity" are Indefinite

50. I disagree with Dr. Byrn as to his definitions of the phrases "permits to obtain reduced ph influence in the digestive tract" and "permits to obtain … reduced influence of viscosity," as those phrases are used in the '632 patent. (Byrn Declaration, Paragraphs 55-70).

51. For a person of ordinary skill in the art to understand the phrase "permits to obtain reduced ph influence," he needs to know the starting point and ending point. In other words, "reduced ph influence," indicates the pH must be relative to some initial pH and that the influence of pH on one type of granule was measurably different than the influence of pH on another or comparative type of granule. Neither the specification nor the file history disclose the critical reference points of pH and extent of influence needed to understand the meaning of "permits to obtain reduced ph influence."

52. A person of ordinary skill in the art would also find the phrase "permits to obtain reduced ph influence" indefinite because it is unclear whether this refers to an increase in pH, a

decrease in pH, buffering capacity, or a completely neutral effect on pH. Moreover, the specification does not describe a pH effect in any specific place within the digestive tract, such as the mouth, pharynx, esophagus, stomach, intestine, etc. The specification does not indicate whether the claimed "reduced pH" influence is found at any of these specific locations within the digestive tract, or throughout the entire digestive tract.

53. Furthermore, there is no correlation in the specification or file history between reduced pH influence in the digestive tract and gastroresistance, as Dr. Byrn and Takeda suggest.

54. Similarly, for a person of ordinary skill in the art to understand the meaning of the phrase "permits to obtain … reduced influence of viscosity," he needs to know the starting point and end point. For there to be a "reduced influence of viscosity," it must be relative to some initial viscosity, which is unknown. Again, the specification nor the file history disclose the critical reference points needed to understand "permits to obtain reduced influence of viscosity."

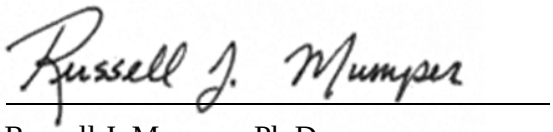
55. While Dr. Byrn relies on the court's earlier claim construction of this term in the Zydus action to mean that "the formulation influences viscosity less than the prior art formulations of record that have excipients increasing viscosity," even this construction is indefinite. While the Zyma references, relied on by Dr. Byrn and the court, define "high viscosity" as an "apparent viscosity at 20 [degrees] C. of 30 to 3000 mPa.s" (Byrn Dec., Ex. 20 (U.S. Patent No. 4,886,669) at Col. 3, ll. 31-35)), those values only identify the starting point for meeting the claim limitation of the '632 patent. Neither the '632 specification nor file history provide any guidance as to how much of that excipient or lack of excipient would be needed to have a reduced influence of viscosity.

56. The meaning of the "reduced influence of viscosity limitation" is further unclear as it remains unknown as to "who" or "what" is permitted "to obtain reduced influence of

viscosity." There is no explanation in the specification or file history as to whether it is the viscosity of the excipients that is reduced, the viscosity of the disintegrated tablet, or the viscosity of fluids in the digestive tract.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct, and if called to testify on the foregoing I could and would testify competently thereto.

Date: June 22, 2012



Russell J. Mumper, Ph.D.